

produce the claimed invention absent some teaching or suggestion supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Accordingly, to establish a *prima facie* case, the Examiner must not only show that the combination includes *all* of the claimed elements, but also a convincing line of reason as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972 (B.P.A.I. 1985). When prior art references require a selected combination to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988). One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

Claim 1 and Claims Depending Therefrom

The Examiner rejected independent claim 1 and dependent claims 8-10 under 35 U.S.C. 103(a) as being rendered obvious by Callahan (U.S. Pat. No. 6,416,328). Claim 1 recites:

A method of identifying training needs for biomedical equipment in a medical facility, the method comprising:
collecting identification and operation data associated with a plurality of biomedical equipment components;
storing the collected data in a central database;
analyzing the operation data to identify at least one operational parameter affected by operator activities with the equipment components; and
identifying a training need based on the analyzed operational parameter.

Some of the recited features of claim 1 that are not disclosed by the Callahan reference are: "collecting identification and operation data associated with a plurality of biomedical equipment components," "analyzing the operation data to identify at least one operational parameter affected by operator activities with the equipment components," and "identifying a training need based on the analyzed operational parameter." As the reference fails to disclose or suggest all of the recited features, the rejection cannot stand.

In the rejection of independent claim 1, the Examiner admitted that the Callahan reference does not disclose that operation data is collected from biomedical equipment components. Under M.P.E.P. § 2143.03, to establish *prima facie* obviousness of a claimed invention, *all* the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970). Moreover, if an independent claim is nonobvious under 35 U.S.C. § 103 then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). As such, the Examiner must consider all of the features recited in the claims. In the rejection, the Examiner admitted that the reference does not disclose operation data, which is recited throughout the claim. In addition, other recited features are not addressed in the rejection, such as "operator activities with the equipment components," for example. Accordingly, the Applicants respectfully request withdrawal of the rejection and reconsideration of all the features recited in the claims.

The Callahan reference is directed to a control system for handling task management and training. Callahan, col. 1, line 64 to col. 2, line 11. The reference further discloses that the Federal Government requires healthcare providers to be in compliance with certain procedures and regulations. Callahan, col. 1, lines 24-44. A system is disclosed that includes a process management means 12 for maintaining a listing of processes that must be performed to be in compliance. Callahan, col. 2, lines

21-27. This system also includes a training means 16 for tracking employee training, classifying employees positions, and coordinating the desired training. Callahan, col. 5, line 60 to col. 6, line 2. A training coordinating means 22 determines the training for an employee from the training that they have received, employee position, and the requirements of the position. Callahan, col. 6, lines 24-34. The system may even include a contractor management means 20 for managing the contractors to ensure that they are in compliance with required processes. Callahan, col. 7, lines 39-52.

The Callahan reference does not disclose that *collecting operation data*, *analyzing the operation data*, and *identifying a training need based on the analyzed operational parameter*. Rather, the portion of the Callahan reference cited by the Examiner is simply a summary of the invention, which describes the tracking and coordinating of the training needs for an employee *based on a predetermined process*, not based upon collected operation data. In addition, the Examiner also cited to a portion of the reference that merely discloses managing the training needs of contractors. The Callahan reference does not disclose *collecting operation data* as this basis for identifying training needs. Moreover, the reference is devoid of any reference to *biomedical equipment* or even the data associated with *biomedical equipment*. Accordingly, the reference cannot disclose or suggest "collecting identification and operation data associated with a plurality of biomedical equipment components," as recited in the claim.

Further, the Callahan reference does not disclose *analyzing the operation data*. In the Callahan reference, the procedures, simply defined in advance, are placed into the storage means 14, which interfaces with the training means 16 to determine additional training for employees. Callahan, col. 7, lines 31-37. However, the Callahan reference does not disclose analyzing any data, but simply implements regulations and procedures that are received, (i.e., provides training *independent* of any consideration of actual operational data). Additionally, here again, as the reference is

devoid of any reference to *biomedical equipment*, the Callahan reference fails to disclose *analyzing the operation data*. Accordingly, the reference cannot disclose or suggest “analyzing the operation data to identify at least one operational parameter affected by operator activities with the equipment components,” as recited in the claim.

Moreover, the Callahan reference does not disclose *identifying a training need based on the analyzed operational parameter*. The Callahan reference discloses determining training needs based on regulations received and placed into the storage means 14. Callahan, col. 7, lines 31-37. Yet, as noted above, the training needs are not identified based on *analyzed operational parameters*. In the rejection, the Examiner asserted that the operational parameters may be developed to solve the training needs of maintenance or janitorial crews. However, the reference actually discloses the contractors, such as maintenance, janitorial crews, or doctors, as being one of the groups that is to be trained because the contractors perform procedures for the provider. Callahan, col. 1, lines 46-48; col. 7, lines 39-46. These groups are included because the provider is ultimately responsible for the compliance with the procedures. Callahan, col. 1, lines 36-48. As such, the passage only relates that contractors may be trained on the procedures in addition to the other employees, which helps to maintain the compliance with the regulations. In addition, a person of ordinary skill in the art would not know how to plan or identify training needs by reading the Callahan reference, and certainly would not be led to analyze operational parameters for that purpose. The reference only discloses that the training needs result from new procedures, not from analyzed operational parameters. Accordingly, the reference fails to disclose or suggest “identifying a training need based on the analyzed operational parameter,” as recited in the claim.

Because the Callahan reference does not disclose or suggest *all* of the recited features, the Examiner has failed to establish that Callahan renders the claimed subject

matter obvious. Therefore, independent claim 1 and its respective dependent claims are believed to be patentable over the Callahan reference.

Claim 23 and Claims Depending Therefrom

The Examiner rejected independent claim 23 under 35 U.S.C. 103(a) as being rendered obvious by Callahan (U.S. Pat. No. 6,416,328). Claim 23 recites:

A method for identifying a training need associated with biomedical equipment in a medical institution, the method comprising:
storing data associated with the equipment in a central database, the stored data including equipment operation data and equipment identification data;
logically grouping the stored equipment operation data in accordance with the corresponding equipment identification data;
analyzing the equipment operation data based on the logical grouping;
generating a presentation of the analyzed equipment operation data in accordance with the logical grouping; and
identifying a training need associated with a particular piece of equipment based on the presentation.

Some of the recited features of claim 23 that are not disclosed by the Callahan reference are: "logically grouping the stored equipment operation data in accordance with the corresponding equipment identification data," "analyzing the equipment operation data based on the logical grouping," and "identifying a training need associated with a particular piece of equipment based on the presentation." As the reference fails to disclose or suggest all of the recited features, the rejection cannot stand.

In the rejection of independent claim 1 and as Applicants assume it is applied to independent claim 23, the Examiner admitted that the Callahan reference does not disclose operation data that is collected from biomedical equipment components. As noted above, under M.P.E.P. § 2143.03, the Examiner must consider the all of the recited features recited in the claims. In addition, other recited features are not even addressed in the

rejection, such as “equipment identification” and “logical groupings,” for example. Accordingly, the Applicants respectfully request withdrawal of the rejection and reconsideration of *all* the features recited in the claims.

The Callahan reference does not disclose that *logically grouping the stored equipment operation data, analyzing the equipment operation data, and identifying a training need associated with a particular piece of equipment*. As noted above, the Examiner admitted that the Callahan reference does not disclose equipment operation data, particularly from biomedical equipment. Again, the Callahan reference fails to disclose *equipment operation data*, and is devoid of any reference to *biomedical equipment* or even the data associated with *biomedical equipment*. Accordingly, the reference cannot disclose or suggest “logically grouping the stored equipment operation data in accordance with the corresponding equipment identification data,” as recited in the claim.

The Callahan reference also does not disclose *analyzing the equipment operation data*. Additional training for employees is determined based on received procedures. Callahan, col. 1, lines 46-48; col. 7, lines 39-46. Moreover, as the reference is devoid of any reference to *biomedical equipment*, the Callahan reference cannot disclose *analyzing the equipment operation data*. Accordingly, the reference cannot disclose or suggest “analyzing the equipment operation data based on the logical grouping,” as recited in the claim.

Moreover, the Callahan reference does not disclose that *identifying a training need associated with a particular piece of equipment*. As discussed previously, the Callahan reference discloses determining training needs based on defined procedures or regulations, not based on *analyzed equipment operational data in a presentation*. Callahan, col. 7, lines 31-37. Again, the reference is devoid of any reference to biomedical equipment and merely mentions maintenance and janitorial crews as part of a contractor group that may be performing procedures for the provider. Further, the

Callahan reference only discloses that the training needs result from new procedures, not from *analyzed equipment operational data in a presentation*. Thus, the reference would not enable a person of ordinary skill in the art to identify for training needs associated with a particular piece of equipment. Accordingly, the reference fails to disclose or suggest “identifying a training need associated with a particular piece of equipment based on the presentation,” as recited in the claim.

Because the Callahan reference does not disclose or suggest *all* of the recited features, the Examiner has failed to establish that Callahan renders the claimed subject matter obvious. Therefore, independent claim 23 and its respective dependent claims are believed to be patentable over the Callahan reference.

Claim 28

The Examiner rejected independent claim 28 under 35 U.S.C. 103(a) as being rendered obvious by Callahan (U.S. Pat. No. 6,416,328). Claim 28 recites:

A system for identifying training needs for biomedical equipment in a medical facility, the method comprising:
 means for collecting identification and operation data associated with a plurality of biomedical equipment components;
 means for storing the collected data in a central database;
 means for analyzing the operation data to identify at least one operational parameter affected by operator activities with the equipment components; and
 means for identifying a training need based on the analyzed operational parameter.

Claim 28 is a system claim whose elements perform functions essentially as set forth in claim 1. Accordingly, claim 28 is clearly patentable for the reasons summarized above with respect to claim 1, which arguments are hereby incorporated here by reference.

Second Rejection Under 35 U.S.C. § 103

The Examiner rejected claims 2-7, 11-22, and 24-27 under 35 U.S.C. 103(a) as being rendered obvious by Callahan (U.S. Pat. No. 6,416,328) in view of Linberg et al. (U.S. Pat. No. 6,497,655). Applicants respectfully traverse this rejection.

Claim 15 and Claims Depending Therefrom

Regarding independent claim 15, this claim recites:

A system for identifying training needs associated with a plurality biomedical equipment components in a medical institution, the system comprising:

a central database configured to store data representative of the equipment components, the stored data including operation data and identification data identifying at least an equipment type;

a data analysis module configured to arrange the operation data into logical groupings and to analyze the operation data based on the logical groupings, the logical groupings including an equipment type grouping; and

a report generator configured to generate a report including an arrangement of the analyzed operation data based on the logical groupings, wherein a training need is identifiable based on the arrangement.

Some of the recited features of claim 15 that are not disclosed by the Callahan reference are: “a data analysis module configured to arrange the operation data into logical groupings and to analyze the operation data based on the logical groupings, the logical groupings including an equipment type grouping” and “wherein a training need is identifiable based on the arrangement.” As the reference fails to disclose or suggest all of the recited features, the rejection cannot stand. In addition, the Examiner has provided no sufficient suggestion or motivation to combine these references.

The Linberg et al. reference is directed to a communication scheme for a remote web-based data center that interacts with a patient having a implantable medical device

(IMD). Linberg et al., col. 8, lines 23-27. The reference further discloses that the IMD is remotely monitored for upgrades or debugging of the system. Linberg et al., col. 8, lines 44-63. The IMD 10 is a microprocessor-based system that provides sensing functions for a patient, such as patient health monitoring. Linberg et al., col. 10, lines 53-66. The IMD 10 communicates patient data to a remote data center 62 to assist in the patient diagnosis. Linberg et al., col. 12, lines 21-47.

Neither the Callahan nor the Linberg et al. reference discloses or suggests *a data analysis module for arranging and analyzing logical groupings of operational data*. As discussed above, the Callahan reference fails to disclose *operation data*. Moreover, the reference is devoid of any reference to *biomedical equipment*, or even the data associated with *biomedical equipment*. Accordingly, the reference cannot disclose or suggest the recited feature. In addition, while the Linberg et al. reference was only cited by the Examiner to teach operational data that is collected by equipment type, the portion of the reference cited by the Examiner simply discloses using operational parameters to upgrade, fine tune, or adjust the implantable medical devices. Nothing in the cited passage discloses or teaches *arranging or analyzing the logical groupings of operation data or logical groupings that include equipment type groupings*. Accordingly, the references fail to teach or disclose “a data analysis module configured to arrange the operation data into logical groupings and to analyze the operation data based on the logical groupings, the logical groupings including an equipment type grouping,” as recited in the claim.

Furthermore, the Callahan and the Linberg et al. references fail to disclose or suggest that *a training need is identifiable based on the analyzed operational data*. The Callahan reference discloses determining training needs based on regulations received and placed into the storage means 14, but the training needs are not based on *analyzed operational parameters*. Callahan, col. 7, lines 31-37. Again, as the reference is devoid of any reference to *biomedical equipment* and does not even

disclose *analyzing data* to determine the training needs, the reference fails to disclose or suggest the recited feature. The Linberg et al. reference does not even disclose *identifying any training needs*. Thus, the Linberg et al. fails to cure the deficiencies of the Callahan reference. Accordingly, the references fail to disclose or suggest "wherein a training need is identifiable based on the arrangement," as recited in the claim.

Moreover, assuming, *arguendo*, such combination of Callahan and the Linberg et al. were even possible, the Examiner has failed to point to a convincing suggestion or motivation that would lead one skilled in the art to modify the Callahan system or the Linberg et al. system as proposed. Indeed, the Examiner merely stated:

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide a method of assessing and identifying training needs in a health care facility that includes collecting identification and operation data, storing the data in a central database, assessing the data to develop a plurality of operational parameters to identify training needs, including data such as equipment type. Equipment type information is required by manufacturers for the registration of medical equipment with the equipment manufacturer, who can offer discounts on training for registered users.

That will not do. The level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 50 U.S.P.Q.2d 1161, 1171 (Fed. Cir. 1999). A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter.

1993). Further, an obviousness rejection may not stand if there is no finding as to the principle or specific understanding within the knowledge of a skilled artisan that would have motivated the skilled artisan to make the claimed invention. *In re Kotzab*, 55 U.S.P.Q.2d 1313, 1318 (Fed. Cir. 2000). As a result, the mere fact that references can be combined or modified (the basic premise for which the Applicants do not accept) does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 16 U.S.P.Q.2d 1430, 1432 (Fed. Cir. 1990).

In the present case, the Examiner's unsupported assertion does not meet the evidentiary standard required for combining references under Section 103. As discussed above, the references fail to disclose various elements and, in fact, do not support the combination. Indeed, the Examiner has impermissibly relied on hindsight, using the teachings of Applicants to find the suggestion to combine the alleged teachings of Callahan and Linberg et al.

In particular, the Callahan reference is directed to a control system for handling task management and training. Indeed, the Callahan reference is strictly related to a process of monitoring and tracking training of regulations and procedures, and is devoid of any reference to biomedical equipment. Conversely, the Linberg et al. reference is directed to a communication scheme for a remote web-based data center interacts with a patient having a implantable medical device (IMD).

The Examiner asserted that the combination would be obvious for assessing and identifying training needs in a health care facility that includes collecting identification and operation data, including data such as equipment type. However, the Callahan reference does not mention equipment at all. In fact, the training needs are disclosed as being based on the Federal Government requirements for healthcare providers to be in compliance with certain procedures and regulations. Callahan, col. 1, lines, lines 24-44.

The problem being solved by Callahan is simply managing training needs to follow the regulations and procedures set forth by the government.

Conversely, the Linberg et al. reference is directed to a communication scheme for a data center and an implantable medical device (IMD). The reference does not disclose or teach identifying training needs associated with the IMD. Accordingly, a person of ordinary skill in the art would not know how to plan or identify training needs by reading the Linberg et al. reference in view of the Callahan reference. Clearly, the references do not suggest the desirability of the combination. Thus, the mere fact that aspects of the references could be combined or modified, (again, a premise not accepted by the Applicants) does not imply any suggestion or motivation to do so. Accordingly, as the references do not support the combination and the Examiner has not pointed to any suggestion or motivation *in the references or in any other art of record* for the proposed combination, the Examiner's alleged combination is unsupported.

Accordingly, because the Examiner has failed to show that the cited references disclose *all* of the claimed elements, as well as a convincing line of reasoning as to why one of ordinary skill in the art would have found the claimed invention obvious in light of the cited reference, the Examiner has failed to establish a *prima facie* case of obviousness. Therefore, independent claim 15 and its dependent claims are believed to be patentable over Callahan in view of Linberg et al.

Claims 2-7 and 11-14

The Examiner rejected claims 2-7 and 11-14 under 35 U.S.C. 103(a) as being rendered obvious by Callahan (U.S. Pat. No. 6,416,328) in view of Linberg et al. (U.S. Pat. No. 6,497,655). Applicants respectfully traverse this rejection.

Applicants believe claims 2-7 and 11-14 are patentable based upon both their dependence on patentable claim 1, and their recited subject matter. In the rejection, the

Examiner admitted that the Callahan reference fails to disclose various features, which the Examiner asserted where disclosed by the Linberg et al. reference. However, as discussed above, the Callahan and Linberg et al. references fail to disclose the all of the recited features of claim 1. As the Linberg et al. reference fails to cure the deficiencies of the Callahan, the references cannot render the claimed subject matter obvious. Accordingly, Applicants respectfully request withdrawal of the Examiner's rejection and allowance of the pending claims 2-7 and 11-14.

Claims 24-27

The Examiner rejected claims 24-27 under 35 U.S.C. 103(a) as being rendered obvious by Callahan (U.S. Pat. No. 6,416,328) in view of Linberg et al. (U.S. Pat. No. 6,497,655). Applicants respectfully traverse this rejection.

Applicants believe claims 24-27 are patentable based upon both their dependence on patentable claim 23, and their recited subject matter. In the rejection, the Examiner admitted that the Callahan reference fails to disclose various features, which the Examiner asserted where disclosed by the Linberg et al. reference. However, as discussed above, the Callahan and Linberg et al. references fail to disclose the all of the recited features of claim 23. As the Linberg et al. reference fails to cure the deficiencies of Callahan, the references cannot render the claimed subject matter obvious. Accordingly, Applicants respectfully request withdrawal of the Examiner's rejection and allowance of the pending claims 24-27.